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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/828,539

04/04/2001

Howard Preissman

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05/12/2006

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,539	PREISSMAN, HOWARD	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-44 and 46-71 is/are pending in the application.
- 4a) Of the above claim(s) 33-39 and 46-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 54-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 40-44 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44 and 54-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Referring to claim 40, both “between about 350u and about 2200u” and “less than 350u” contain new matter. Applicant only has support for “between about 350u and 2200u” and “between about 120u and 350u”. By reciting the current claim language, the applicant has altered the range to one that is not fully supported by the specification. For instance, between about 350u and 2200u may be interpreted to be 350u-2200u or 349u-2200u and between about 350u and about 2200u may be interpreted to be 349u-2201u. Further, less than 350u may be interpreted to be 0-349u, however applicant does not have support for 0u-119u, nor does the applicant have support for excluding 350u from the range. Claims 41-44, 54-61, and 70-71 depend upon claim 40 and inherit all problems associated with the claim.

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Referring to claims 60 and 67, “about 1% to about 10%” is considered new matter.

Although the applicant has support in two examples, the use of 1% and 10% separately, a range is never disclosed, therefore, there is no support for 2-9%, further, there is no support that says 10% is a maximum optimal range or 1% as an optimum minimal range.

Referring to claim 62, “substantially between 350u and 2200u” is considered new matter. Applicant only has support for “between about 350u and 2200u”. By reciting the current claim language, the applicant has altered the range to one that is not fully supported by the specification. “Substantially” has different interpretation than “about”. Claims 63-69 depend upon claim 62 and inherit all problems associated with the claim.

Referring to claim 63, “less than 350u” is considered new matter for the same reasons are described above when referring to claim 40.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 57, the limitations of a liquid contrast agent and soluble agent do not further limit the independent claim, but instead alter the claim. Independent claim requires contrast particles. It is unclear how liquid and soluble agents are in the particulate form.

Claim 71 recites the limitation "radiopaque tracer particles" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change the above to recite --contrast particles--.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62, 64, 65, 68, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (US 5,258,028, cited previously). Referring to claim 62, Ersek discloses an injectable composition (see fig.3, 4; col.2, lines 12-21; col.9, lines 21-25) comprising a flowable matrix (physiologic vehicle 31; col.2, lines 47-52, 67-68) and radiopaque tracer particles (30; disclosed to be radiopaque, col.3, lines 15-19; col.10, lines 22-27) having a size of between about 350 microns and 2200 microns (col.2, lines 35-39), and wherein the particles are individually visible during implantation (inherently Ersek's particles are individually visible, since they are the same size as the applicant's particles, therefore, would have to be just as visible as the applicant's particles).

Referring to claim 64, Ersek discloses the claimed flowable matrix materials, such as collagen or polymer based materials (physiologic vehicle, col.2, lines 47-52, 67-69).

Referring to claim 65, Ersek discloses the radiopaque particles to comprise barium compounds (col.10, lines 22-28).

Referring to claims 68-69, Ersek discloses the radiopaque particles to be sized between about 570u and 2200u, or between about 450u and 1600u (all ranges fall within Ersek's disclosed range of between about 30u and 3000u; col. 2, lines 35-39).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER